

SOLICITATION, OFFER AND AWARD1. THIS CONTRACT IS A RATED ORDER
UNDER DPAS (15 CFR 700)

RATING

PAGE OF PAGES

1 38

2. CONTRACT NUMBER

3. SOLICITATION NUMBER

4. TYPE OF SOLICITATION

☐ SEALED BID (IFB)☒ NEGOTIATED (RFP)

5. DATE ISSUED

6. REQUISITION/PURCHASE
NUMBER

7. ISSUED BY

CODE

DHHS/FDA/OFACS/DCPM/ORA Support and Assistance
 Management Branch, HFA-521
 5600 Fishers Lane, Room 2129
 Rockville, Maryland 20857

8. ADDRESS OFFER TO (If other than Item 7)

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and 3 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in 5630 Fishers Lane, Room 2129 until 4:30P local time Rockville, MD 20857 (Hour) (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR
INFORMATION
CALL:

A. NAME

B. TELEPHONE (NO COLLECT CALLS)

AREA CODE

NUMBER

EXT.

C. E-MAIL ADDRESS

11. TABLE OF CONTENTS

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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT ☒ 10 CALENDAR DAYS (%) 20 CALENDAR DAYS (%) 30 CALENDAR DAYS (%) CALENDAR DAYS (%)
 (See Section I, Clause No. 52-232-8)

14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):

AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR

CODE _____ FACILITY _____

16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)

15B. TELEPHONE NUMBER

AREA CODE	NUMBER	EXT.

☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.

17. SIGNATURE

18. OFFER DATE

AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED

20. AMOUNT

21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:

☐ 10 U.S.C. 2304(c) () ☒ 41 U.S.C. 253(c) (1)

23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified) ☒ ITEM

24. ADMINISTERED BY (If other than Item 7) CODE _____

25. PAYMENT WILL BE MADE BY CODE _____

26. NAME OF CONTRACTING OFFICER (Type or print)

27. UNITED STATES OF AMERICA

(Signature of Contracting Officer)

28. AWARD DATE

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTSB-1 - Background and Objectives

In performing the work as described in detail in Section C, C-1 - Scope of Work, the contractor shall consider the following:

A. Background:

This contract is designed to obtain State assistance in inspectional coverage of food establishments.

B. Objectives:

1. To obtain inspections in selected food establishments to determine compliance with the Federal Food, Drug and Cosmetic (FD&C) Act, state law, or both;
2. To collect factory and official follow-up samples as dictated by inspectional observations;
3. To analyze any samples collected using the Association of Official Analytical Chemists (AOAC) or Food & Drug Administration (FDA) methodology;
4. To furnish the Government with reports of the inspections and sample examinations as well as reports on any compliance follow-ups and corrections achieved by action the contractor takes under its own program.

B-2 - Compensation

- A. As consideration for full performance of the work stated in Part I, Section C, C-1 - Scope of Work, the Government shall pay the contractor a total fixed price of \$_____.
- B. Payment up to the full amount of this contract shall be contingent upon receipt and acceptance by the Government of inspection reports and proper invoices as required by Part I, Section F, F-1 - Reports/Deliverables and Section G, G-3 - Invoice Submission, and in accordance with the following schedule:

Schedule

<u>Item</u>	<u>Unit Price</u>	<u>No. of Units</u>	<u>Total</u>
Food Inspections	\$ _____	_____	\$ _____

SECTION B (continued)

HACCP

Inspections \$ _____

Samples \$ _____

*Inspection visits are _____ included or _____ excluded in the Number of Units.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENTC-1 - Scope of Work

Independently and not as an agent of the Government, the contractor shall furnish the necessary personnel, materials, services, facilities, except as provided in the schedule, and otherwise do all things necessary for or incident to the performance of the work as described below:

A. Coverage

The Contractor shall conduct establishment inspections, consisting of both initial inspections and necessary reinspections and visits (when included).

The establishments available for coverage by the contractor are those that come under the jurisdiction of both the State and FDA, i.e., they are included in FDA's "Firm Establishment Identifier" (FEI). To preclude duplication with inspections to be accomplished by FDA personnel, the specific establishments to be inspected by the contractor will be planned and/or scheduled by the appropriate FDA regional/district office, in conjunction with the contractor.

Assignment of establishments by FDA for coverage under the contract will take into consideration the following priorities (from the FDA Compliance Programs):

B. Inspection Priorities

Coverage of firms is to be consistent with the Food Safety Initiative (FSI) objective of reducing foodborne outbreaks by determining compliance with various regulations that cover potentially high risk products, such as unpasteurized juices, non-Grade A dairy products, and eggs, where the contractor has jurisdiction over those establishments.

SECTION C (continued)

1. Firms classified Official Action Indicated (OAI), (or Voluntary Action Indicated-3 prior to May 1994) one or more times during the past six (6) years.

2. Use District intelligence (e.g., past inspections, industry information, complaints, media, etc.) in selecting firms that could have potential problems or which produce a product with a history of known or potential health hazard problems. Examples of such firms are producers of:
 - cream filled baked goods,
 - ice cream,
 - cheese and cheese products,
 - other items which receive little or no further processing before consumption by the consumer (i.e., ready-to-eat, heat & serve),
 - products in which time/temperature problems could occur (e.g. commodities which support microbial growth when abused), and
 - fish and fishery products manufacturers.

- 2a. Inspections of seafood processors are to be performed under the CURRENT Domestic Fish and Fishery Products Inspection Program (C.P. 7303.842), in addition to coverage for compliance with the Good Manufacturing Practices regulations and other relevant regulations. Such inspections shall be performed only by state inspectors that have been properly trained in the principles of HACCP (e.g. Seafood HACCP Alliance three day course or its equivalent) and the performance of a HACCP-based inspection (e.g. two day Seafood HACCP Regulator course).

3. Firms selected on the basis of the violative history of the overall industry.

4. Firms never inspected by FDA or never inspected under the Food Safety Program should be given precedence over firms previously inspected or inspected under the Food Safety Program and classified as No Action Indicated (NAI).

5. **No more than 15% of the number of inspections included in the contract shall be of food storage warehouses, i.e. those designated as establishment type "warehouse (w)" only. Those**

SECTION C (continued)

establishments that are selected are to be ones that have had previous violative inspections or complaints. Also included in the selection are warehouses that are considered "high risk".

C. Frequency of Inspection

The inspections conducted under this contract shall be scheduled in accordance with the provisions of the FDA Compliance Programs referenced below. The following table is a summary of the planned inspection frequencies:

<u>Firm</u>	<u>Frequency of Inspection</u>
Firms producing products with a substantial potential for risk, such as processors of low acid/acidified foods, and certain ready to eat fish or fisheries products.	Once every year.
Firms for which a specific frequency is not stated in the Compliance Program, including bottled water.	Not more than once every 2 years.
Firms with low risk potential, including low risk seafood firms.	Not more than once every 4 years.

Inspections for cause may be scheduled more frequently than indicated in the above table, e.g., reinspections necessary as a follow-up to Official Action Indicated (OAI) findings, or follow-up to a complaint. Shellfish establishments which are a state inspection responsibility under the National Shellfish Sanitation Program are not eligible for coverage under this contract.

Inspection visits are encountered where an inspection is attempted and the establishment is found to be out of business, not OEI, or a complete inspection cannot be accomplished. Information on inspection visits will be submitted on a computer generated coversheet form.

Joint inspections with FDA personnel to achieve nationwide uniformity, training, evaluation, etc., will be planned from time

SECTION C (continued)

to time and will be included within the inspections to be accomplished by the Contractor. The FDA regional/district offices will provide technical guidance to the Contractor.

Compliance actions are not provided for under this contract. However, it is anticipated the Contractor will pursue vigorously any necessary compliance follow-up to violative conditions encountered during inspections made under this contract. Such actions may include stop-sales, administrative plant closures or orders, warnings, license revocations, court actions, etc. Where appropriate correction has not been achieved by the Contractor, FDA has the option to initiate compliance actions under the FD&C Act as warranted by the facts.

D. Method of Coverage

The activities under the contract will be conducted using procedures, techniques, and reporting forms specified by FDA. The FDA inspections are conducted in accordance with the applicable sections of the following current FDA Compliance Programs:

Domestic Food Safety Program, (C.P. 7303.803)
 Domestic Fish and Fishery Products Inspection (C.P. 7303.842).
 **
 Domestic Acidified and Low-Acid Canned Foods (C.P. 7303.803A)
 Domestic and Imported Cheese & Cheese Products (C.P. 7303.037)
 NLEA and General Food Labeling Program, (FY '98/99),
 (CP7321.005)

These programs are incorporated by reference as guidance for the conduct of contract inspections. The Government will furnish copies to the Contractor where appropriate.

The Contractor shall conduct inspections of food establishments to determine compliance with the food provisions of the Federal FD&C Act, or both state law and the FD&C Act. The inspections will generally be accomplished under the authority of the state's law. The major inspectional emphasis will be placed upon determining significant insanitary conditions and practices which may render the food injurious to health, particularly those involving the introduction, lack of controls, and/or growth promotion of pathogenic organisms and other conditions which may have caused food to become filthy, putrid, decomposed or contaminated with foreign objects which present a reasonable possibility of causing the contamination of food. Compliance with the Federal FD&C Act, Section 402(a)(3) and (4) and regulations thereunder, e.g., the

SECTION C (continued)

Good Manufacturing Practices (GMP) Regulations (21 CFR 110); or Section 10(a)(3) and (4) of the Uniform State Food, Drug and Cosmetic Bill, will be determined. Where applicable, use the Hazard Analysis and Critical Control Point (HACCP) concept to evaluate a firm's quality assurance program and its year-round operations.

Other factors which could affect the safety of a food product should also be covered. During an inspection of a food manufacturer, the use of color and food additives will be determined and reported as detailed in the above mentioned compliance program. The specific additives are identified in the Compliance Program.

Bottled water plants are inspected to determine compliance with the bottled water GMP regulation, [21 CFR 129] that includes testing requirements. If indicated by inspectional observations, one finished product sample may be collected to determine compliance with the standard of identity and quality for bottled water in 21 CFR 165.110 (formerly 103.35; See FEDERAL REGISTER 60 57076-57130, Effective date: May 13, 1996). The contractor shall analyze the sample for: microbiological quality, benzene and chloroform via a screen for volatile organic compounds, and for the heavy metals lead, cadmium, mercury, and arsenic. Sample results shall be reported to the FDA district.

The inspection reports should detail the conditions found with sufficient narrative to enable an assessment of the significance of any objectionable conditions or practices found. Where microbiologically oriented inspections are conducted, a more detailed description of the manufacturing process, routes of contamination, etc., will also be made.

Nutrition labeling regulations as required under the Nutrition Labeling and Education Act of 1990 (NLEA) includes specific requirements for the nutrition labeling of foods. All food products, with the exception of exempt foods, labeled on or after August 8, 1994 are subject to the NLEA regulations.

During contract inspections of manufacturers, labelers, or relabelers, states trained in the NLEA regulatory enforcement strategy will review labels being used to determine if they are in compliance with the nutrition labeling regulations. The inspections will also include the determination and reporting on the exempt status of the firm or labels, and whether the products are shipped in interstate commerce. Physical samples of products to determine compliance with NLEA requirements will not be collected unless specifically requested by the Co-Project Officer.

SECTION C (continued)

The label review will be conducted in accordance with the current Compliance Program, and the current guidelines for State Coverage of NLEA Under Food Inspection Contracts, included as Attachment A.

The label(s) shall be submitted with the inspection report except that collection and submission of non-violative labels will not be required when the Co-Project Officer determines the contractor is accurately identifying the violations emphasized in the assignment/program. All follow-up action, including regulatory actions, shall be coordinated with the appropriate FDA district.

****** Inspections of seafood processors shall be conducted under the current guidance of FDA's Domestic Fish and Fishery Products Compliance Program (C.P. 7303.842) which includes coverage to determine compliance with the Seafood HACCP regulation as well as to address violations of the FD&C Act and other regulations under the Act that relates to food sanitation, wholesomeness, and labeling including nutritional content labeling. Such inspections shall only be performed by state inspectors that have been trained in HACCP (i.e., have attended a Seafood Alliance 3-day course or its equivalent and have successfully completed the Seafood HACCP Regulator course including passing the course examinations(s).

Inspections of seafood processors shall include completion of the multi-part form "Domestic Seafood HACCP Report" (Form FDA 3501) which is to be promptly submitted to FDA/CFSAN upon completion and classification of each seafood inspection. These forms should preferably be faxed to FDA/CFSAN. Faxes of Form FDA 3501 must be sent from a fax line previously registered with CFSAN (for security reasons). If the contractor is unable to fax the form, the original copy shall be mailed overnight delivery to:

Food and Drug Administration
CFSAN/Division of Enforcement and Programs
Domestic Programs Branch, HFS-636, Room 5157
200 C. Street, SW
Washington, DC 20204
ATTN: Domestic Fish and Fishery Products Monitor

Inquiries regarding submission of Form FDA 3501, including registering a fax number, are to be directed to FDA's Office of Seafood at (202) 418-3150.

Samples for surveillance purposes and HACCP Verification samples (as described in FDA's seafood compliance program) are **NOT** to be collected by contractor.

SECTION C (continued)

E. Samples

Samples of raw materials, processed foods, etc., necessary to determine compliance shall be collected by the Contractor. Such samples will be collected to demonstrate, through laboratory analysis, violations of State and/or Federal Law and shall consist of sufficient units, size, etc., necessary for the official laboratory methodology to be used. FDA will make appropriate sampling schedules available to the contractor upon request.

The samples will be analyzed using AOAC methodology if available, or by other appropriate methodology such as those in FDA's analytical manuals.

F. Quality Control

FDA will evaluate the Contractor's overall performance throughout the contract period. This will be accomplished by a variety of techniques. Inspectional performance evaluation will include review of reports, joint inspections (included as contract inspections), and independent reinspection by FDA. Sufficient independent quality control reinspections (audits) may be made by FDA to enable an evaluation of the overall performance of the Contractor. Such inspections will be scheduled by the FDA district office.

Analytical support evaluation will include, where appropriate, review of sample reports, joint bench work in FDA or State laboratories, on-site review of State laboratory facilities and equipment, and participation in split sample programs, wherein microbiological and microanalytical (filth) split samples will be analyzed by State laboratories supporting contract inspections. These split samples will be a part of the FDA-State Laboratory Quality Assurance Programs.

Results of the FDA quality assurance review that pertain to the Contractor will be furnished to the Contractor.

G. Confidentiality and Disclosure(Release of Information)

Official FDA information generated by the contractor in the performance of this contract may not be released to the public without prior approval of the local FDA Regional/District office.

SECTION D - PACKING AND MARKING

D-1 - Marking Instructions for Reports

This section is not applicable to this solicitation/contract.

SECTION E - INSPECTION AND ACCEPTANCE

E-1 - Inspection and Acceptance

Pursuant to the appropriate inspection clause as provided below, final inspection and acceptance of all items called for by this contract shall be made by the FDA Contracting Officer at the Food and Drug Administration, ORA Support and Assistance Management Branch, HFA-521, 5600 Fishers Lane, Room 2129, Rockville, Maryland 20857.

E-2 - FAR 52.252-2, Clauses Incorporated by Reference. (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.arnet.gov/far>

I. FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1)
CLAUSES

FAR 52.246-4, Inspection of Services - Fixed Price. (AUG 1996)

SECTION F - DELIVERIES OR PERFORMANCE

F-1 - Reports/Deliverables

The contractor shall submit the following reports/deliverables by the due dates indicated:

- A. Inspection Reports- SUBMIT NO LATER THAN 15 WORKING DAYS AFTER THE DATE OF THE STATE INSPECTION TO THE FDA DISTRICT OFFICE

SECTION F (continued)

The contractor shall complete the detailed Inspection Report for the appropriate industry, and the Computer Generated Coversheet,

(Form FDA-481-CG), Parts A, C, and E. (**NOTE:** The HACCP component {PAC 03S002} and the non-HACCP component {PAC 03S001} are to be accounted for separately on the coversheet.) For HACCP Seafood inspections, the Contractor shall submit Form FDA 3501 as specified in Section C, C-1 - "Scope of Work", paragraph D (which is to be promptly submitted to FDA/CFSAN upon completion and classification of each seafood inspection). The Contractor shall use the FDA Product Code List to complete the appropriate sections of the Coversheet, including Part C: Products Covered, where the products inspected will be recorded. Also, corrective action shall be reported and coded on Part E of the coversheet under the newly revised Compliance Achievement Reporting System which replaces the Voluntary Correction Reporting System. The Government will furnish the necessary FDA forms.

For all seafood inspections performed under "Domestic Fish and Fishery Products Inspection Program"(C.P. 7303.842), submit the following to the FDA District:

Form FDA 3501(if mailed to CFSAN the form will lack the original copy);

Establishment Inspection Report (EIR);

List of Observations (Form FDA 483) or state's equivalent;

Inspection Cover Sheet (Form FDA 481(A)-CG)
Products Covered Form (Form FDA 481 (c)-CG);

Firm's HACCP Plan; and

Other documents that may be needed to support violations of the HACCP Regulations (for inspections of facilities that do not have a HACCP Plan or an inadequate plan, a flow chart of the product(Points (CCPs) and determine if the CCPs are being adequately monitored.) per Compliance Program 7303.842, Part III.

All the information and documents listed above obtained during i federal government. Disclosure of such information shall only be made by FDA pursuant to the Freedom of Information Regulations in 21 CFR 20.1.
SECTION F (continued)

B. Sample Reports-SUBMIT UPON COMPLETION TO FDA DISTRICT OFFICE

All samples analyzed shall be reported to FDA on forms used by the state. Additionally, worksheets or other more detailed information on the analyses shall be submitted to FDA for those

samples found not to be in compliance with current FDA administrative guidelines, or where a question exists whether or not a sample is violative.

C. Compliance Action Reports-SUBMIT UPON COMPLETION TO FDA DISTRICT OFFICE

Copies of the documents used by the state to record compliance actions shall be submitted.

D. Quarterly Summary Report- SUBMIT NO LATER THAN 30 DAYS AFTER END OF EACH 90 DAY REPORTING PERIOD TO:

1. One copy to: FDA District Office
2. Two copies to:
Food and Drug Administration
ORA Support & Assistance Management Branch
5600 Fishers Lane, Rm. 2129, HFA-521
Rockville, MD 20857

NOTE: IF VOUCHERS/INVOICES ARE SUBMITTED MORE OFTEN THAN QUARTERLY, SUBMIT ADDITIONAL PROGRESS REPORTS, WHICH COVER THE PERIODS VOUCHERED.

For each 90 day period of the contract (based upon the performance period), a Quarterly Summary Report (Form FDA-2684) on the inspections, samples, and actions shall be prepared. Included with the report shall be the contract number, a list of the establishments inspected specifying the name and city of the firm inspected, inspection date, and number of samples collected. Where visits were encountered, they should also be noted. NOTE: In those periods where no inspections were performed a report showing no inspections is required.

F-2 - Period of Performance

Performance of this contract shall begin on _____, and shall not extend beyond _____.

SECTION G - CONTRACT ADMINISTRATION DATA

G-1 - Project Officer

The Project Officer responsible for the acceptance of work provided hereunder will be designated by separate

correspondence.

G-2 - Project Director

The performance of the work required by this contract will be conducted for the State under the direction of _____.

G-3 - INVOICE SUBMISSION

1. Fixed Price - Quarterly (Letter of Credit)

_____ Letter of Credit No: _____

OR

2. Fixed Price - Quarterly

The Contractor shall submit vouchers or invoices in accordance with the FAR 52.232-25 "Prompt Payment (JUN 1997)," and FAR 52.232-33 "Payments by Electronic Funds Transfer - Central Contractor Registration (May 1999), in Part II, Section I.

A. In accordance with clause 52.232-33, **all** payments made under this contract shall be made using electronic funds transfer through the Automated Clearing House (ACH). The Contractor shall provide the following information to the Food and Drug Administration, Office of Financial Management, Systems Accounting Branch, HFA-120, 5600 Fishers Lane, Rockville, MD 20857 no later than 14 days prior to submission of the first invoice:

1. Routing transit number of the financial institution receiving payment.
2. Number of account to which funds are to be deposited.
3. Type of depositor account ("C" for checking, "S" for savings).

SECTION G (continued)

B. An original and five (5) copies shall be submitted to the attention of the designated Contract Specialist at the following address:

DHHS/FDA/ORR Support and Assistance Management

Branch, HFA-521
 5600 Fishers Lane, Room 2129
 Rockville, Maryland 20857

C. In addition, one informational copy of all vouchers shall be submitted to the Co-Project Officer in the Regional/District Office designated by separate correspondence.

G-4 - Government Furnished Materials

The following forms required for use in the performance of the services required hereunder will be furnished by the Government. Delivery will be made in a timely manner to the Contractor's facility, such that the required services can be performed within the effective dates of the contract.

<u>Forms No.</u>	<u>Title</u>
FD-2679	Food Warehouse Inspection Report
FD-2680	Grain and Bean Storage Facility Inspection Report
FD-2681	Bakery Inspection Report
FD-2682	Beverage Plant Inspection Report
FD-2966	Food GMP Inspection Report
FDA-481-CG	Computer Generated Coversheet (Parts A, C. and E)
FDA-3501	Domestic Seafood HACCP Report

SECTION H - SPECIAL CONTRACT REQUIREMENTS

This Section is not applicable to this solicitation/contract.

SECTION I - CONTRACT CLAUSES

I-1 - 52.252-2 Clauses Incorporated by Reference.(FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.arnet.gov/far>

A. Federal Acquisition Regulation (FAR) (48 CFR Chapter 1)
Clauses

<u>FAR</u> <u>Clause No.</u>	<u>Title & Date</u>
52.203-3	Gratuities (APR 1984)
52.203-5	Covenant Against Contingent Fees (APR 1984) Government. (JUL 1995)
52.203-7	Anti-Kickback Procedures (JUL 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (JAN 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (JAN 1997)
52.203-12	Limitations on Payments to Influence Certain Federal Transactions (JUN 1997)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (JUN 1996)
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (JUL 1995)
52.215-8	Order of Precedence-Uniform Contract Format (OCT 1997)
52.222-3	Convict Labor (AUG 1996)
52.222-21	Prohibition of Segregated Facilities (FEB 1999)
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APR 1998)
52.222-36	Affirmative Action For Workers with Disabilities (JUN 1998)
52.223-6	Drug-Free Workplace (JAN 1997)
52.227-1	Authorization and Consent (JUL 1995)
52.229-4	Federal, State, and Local Taxes (Noncompetitive Contract) (JAN 1991)
52.232-9	Limitation on Withholding of Payments (APR Interest (JUN 1996)
52.232-17	
52.232-23	Assignment of Claims (JAN 1986)

Section I (continued)

- 52.232-25 Prompt Payment (JUN 1997)
- 52.232-33 Payments by Electronic Funds Transfer - Central Contractor Registration (MAY 1999)
- 52.233-1 Disputes (DEC 1998)
- 52.233-3 Protest After Award (AUG 1996)
- 52.242-1 Notice of Intent to Disallow Costs (APR 1984)
- 52.243-1 Changes - Fixed Price (AUG 1987) - Alternate V (APR 1984)
- 52.245-2 Government Property (Fixed-Price Contracts) (DEC 1989) - Alternate I (APR 1984)
- 52.246-23 Limitation of Liability (FEB 1997)
- 52.249-5 Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (SEPT 1996)

B. Department of Health and Human Services Acquisition Regulation (HHSAR) (48 CFR Chapter 3) Clauses

- 352.202-1 Definitions (JAN 1997)--Alternate
- 352.232-9 Withholding of Contract Payments (APR 1984)
- 352.249-14 Excusable Delays (APR 1984)
- 352.270-4 Pricing of Adjustments (APR 1984)
- 352.270-6 Publication and Publicity (JUL 1991)
- 352.270-7 Paperwork Reduction Act (APR 1984)

SECTION J - LIST OF ATTACHMENTS

The following attachments are incorporated into this solicitation/contract.

Attachment 1 - Guidelines for State Coverage of NLEA Under Food Inspection Contracts

Attachment 2 - Disclosure of Lobbying Activities

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS
OF OFFERORS

Representations and Certifications

To Be Completed by the Offeror/Bidder: (The Representations and Certifications must be executed by an individual authorized to bind the offeror/bidder.)

The offeror/bidder makes the following Representations and Certifications as part of its proposal (check or complete all appropriate boxes or blanks on the following pages).

Solicitation No.

Name of Offeror/Bidder

Signature of Authorized Individual

Typed Name of Authorized Individual

Date

NOTE: The penalty for making false statements in offers or bids is prescribed in 18 U.S.C. 1001.

Certification for Contracts, Grants, Loans and Cooperative Agreements

K-1 - 52.252-1 Solicitation Provisions Incorporated by Reference.
(FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blanks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of these provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its proposal or

SECTION K- Representations, Certifications and Other Statements
of Offerors (continued)

offer. Also, the full text of a solicitation provision may be
accessed electronically at this/these address(es):

<http://www.arnet.gov/far>

52.203-11 Certification and Disclosure Regarding Payments to
Influence Certain Federal Transactions. (APR 1991)

52.204-5 Women-Owned Business (Other Than Small Business. (MAY
1999)

K-2 - Solicitation Provisions Incorporated in Full Text

52.204-3 Taxpayer Identification. (OCT 1998)

(a) Definitions.

"Common parent," as used in this provision, means that
corporate entity that owns or controls an affiliated group of
corporations that files its Federal income tax returns on a
consolidated basis, and of which the offeror is a member.

"Taxpayer Identification Number (TIN)," as used in this
solicitation provision, means the number required by the Internal
Revenue service (IRS) to be used by the offeror in reporting
income tax and other returns. The TIN may be either a Social
Security Number or an Employer Identification Number.

(b) All offerors are required to submit the information required
in paragraphs (d) through (f) of this provision to comply with
debt collection requirements of 31 U.S.C. 7701(c) and 3325(d),
reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M and
implementing regulations issued by the IRS. If the resulting
contract is subject to the reporting requirements described in
Federal Acquisition Regulation (FAR) 4.904, the failure or
refusal by the offeror to furnish the information may result
in a 31 percent reduction of payments otherwise due under the
contract.

(c) The TIN may be used by the Government to collect and report
on any delinquent amounts arising out of the offeror's
relationship with the Government (31 U.S.C. 7701(c)(3)). If
the resulting contract is subject to the payment reporting
requirements described in FAR 4.904, the TIN provided
hereunder may be matched with IRS records to verify the
accuracy of the offeror's TIN.

SECTION K- Representations, Certifications and Other Statements
of Offerors (continued)

(d) Taxpayer Identification Number (TIN).

☐ TIN: _____

☐ TIN has been applied for.

☐ TIN is not required because:

☐ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the U.S. and does not have an office or place of business or a fiscal paying agent in the U.S.;

☐ Offeror is an agency or instrumentality of a foreign government;

☐ Offeror is an agency or instrumentality of a Federal Government.

(e) Type of organization

☐ Sole proprietorship;

☐ Partnership;

☐ Corporate entity (not tax-exempt);

☐ Corporate entity (tax-exempt)

☐ Government entity (Federal, State, or local);

☐ Foreign government;

☐ International organization per 26 CFR 1.6049-4;

☐ Other _____.

(f) Common Parent.

☐ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.

☐ Name and TIN of common parent:

Name _____

TIN _____

52.204-6 Data Universal Numbering System (DUNS) Number. (JUN 1999)

(a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" followed by the DUNS number which identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet information Services.

(b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one. A DUNS number will be provided immediately by telephone at no charge to the offeror. For information on obtaining a DUNS number, the

SECTION K- Representations, Certifications and Other Statements
of Offerors (continued)

offeror should call Dun and Bradstreet at 1-800-333-0505. The offeror should be prepared to provide the following information:

- (1) Company name.
- (2) Company address.
- (3) Company telephone number.
- (4) Line of business.
- (5) Chief executive officer/key manager.
- (6) Date the company was started.
- (7) Number of people employed by the company.
- (8) Company affiliation.

(c) Offerors located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet Home Page at <http://www.customerservice@dnb.com>. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at globalinfo@mail.dnb.com.

52.209-5 Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters. (MAR 1996)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that-

(i) The Offeror and/or any of its Principals-

(A) Are _____ are not _____ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have _____ have not _____, within a 3-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are _____ are not _____ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with,

SECTION K- Representations, Certifications and Other Statements
of Offerors (continued)

commission of any of the offenses enumerated in subdivision
(a)(1)(i)(B) of this provision.

(ii) The Offeror has _____ has not _____, within a 3-year period
preceding this offer, had one or more contracts terminated for
default by any Federal agency.

(2) "Principals," for the purposes of this certification, means
officers; directors; owners; partners; and, persons having
primary management or supervisory responsibilities within a
business entity (e.g., general manager; plant manager; head of
a subsidiary, division, or business segment, and similar
positions).

This certification concerns a matter within the jurisdiction of
an agency of the United States and the making of a false,
fictitious, or fraudulent certification may render the maker
subject to prosecution under section 1001, title 18, United
States Code.

(b) The Offeror shall provide immediate written notice to the
Contracting Officer if, at any time prior to contract award, the
Offeror learns that its certification was erroneous when
submitted or has become erroneous by reason of changed
circumstances.

(c) A certification that any of the items in paragraph (a) of
this provision exists will not necessarily result in withholding
of an award under this solicitation. However, the certification
will be considered in connection with a determination of the
Offeror's responsibility. Failure of the Offeror to furnish a
certification or provide such additional information as requested
by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to
require establishment of a system of records in order to render,
in good faith, the certification required by paragraph (a) of
this provision. The knowledge and information of an Offeror is
not required to exceed that which is normally possessed by a
prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a
material representation of fact upon which reliance was placed

SECTION K- Representations, Certifications and Other Statements
of Offerors (continued)

when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

52.215-6 Place of Performance. (OCT 1997)

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, _____ intends, _____ does not intend (check applicable block) to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance
(Street Address, City,
County, State, Zip Code)

Name and address of
Owner and Operator of the
Plant or Facility if Other
than Offeror or Quoter

52.219-1 Small Business Program Representation. (OCT 1998)

(a)(1) The standard industrial classification (SIC) code for this acquisition is 7389.

(2) The small business size standard is \$5.0 million.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

SECTION K - Representations, Certifications and Other Statements of Offerors (continued)

(b) Representations.

(1) The offeror represents and certifies as part of its offer that it ____ is, ____ is not a small business concern.

(2) (Complete only if offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it ____ is, ____ is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if offeror represented itself as a small business concern in block (b)(1) of this section. The offeror represents as part of its offer that it ____ is, ____ is not a women-owned small business concern.

(c) Definitions. Women-owned small business concern, as used in this provision, means a small business concern--

(1) Which is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice. (1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small or small disadvantaged business concern in order to obtain a contract to be awarded under the preference programs established pursuant to sections 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both

(ii) Be subject to administrative remedies, including suspension and debarment; and

SECTION K- Representations, Certifications and Other Statements of Offerors (continued)

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

52.222-22 Previous Contracts and Compliance Reports. (FEB 1999)

The offeror represents that -

(a) It ___ has, ___ has not participated in a previous contract or subcontract subject either to the Equal Opportunity clause of this solicitation;

(b) It ___ has, ___ has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

52.222-25 Affirmative Action Compliance. (APR 1984)

The offeror represents that (a) it ___ has developed and has on file, ___ has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it ___ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

L-1 - General Instructions

Your proposal must be prepared in accordance with the General Instructions, Business Proposal Instructions, and the Statement of Work contained in Part I, Section C of the Request for Proposal (RFP).

The following instructions establish the acceptable minimum requirements for the format and content of proposals. Special attention is directed to the requirements for a business proposal to be submitted in accordance with these instructions.

The penalty for making false statements in offers is prescribed in 18 USC 1001.

A. Submission of Proposals: All documents required for responding to this RFP should be placed in the following order when submitting proposals:

1. COVER PAGE - with RFP title, RFP number, and name of organization. Also, indicate on cover page either:

(a) ORIGINAL PROPOSAL (signed)

(b) COPY OF PROPOSAL

2. BUSINESS PROPOSAL - Your proposal shall include cost and pricing data in sufficient detail to establish the reasonableness of your proposed price/cost. In addition, you must submit one (1) copy of the Representations and Certifications (Section K).

In addition, one (1) copy of the business proposal shall be submitted to the Co-Project Officer in the FDA Regional/District Office.

B. Alternate Proposals. You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements, provided that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interest of the Government. Alternative proposals, or deviations from any requirement of this RFP, shall be clearly identified.

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

C. Restriction on Disclosure and Use of Data (APR 1984) (HHSAR 352.215-12). The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:

LEGEND

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc., by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI Officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act. If a contract is awarded to the offeror as a result of, or in connection with the submission of this proposal, the

Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

D. Your proposal must stipulate that it is predicated upon all the terms and conditions of this RFP.

E. It is understood that your proposal will become part of the official file.

L-2 - Business Proposal Instructions

Your business proposal shall consist of three parts: Cost and pricing data, other administrative data, and representations and certifications.

The business proposal should be specific and complete in every detail. To reduce subsequent requests to offerors for additional data, the following paragraphs provide guidance on preparing your business proposal.

A. Cost or Pricing Data

You must submit, as a minimum, cost proposals fully supported by cost and pricing data adequate to establish the reasonableness of the proposed amount.

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

Submit a detailed breakdown of estimated costs for each task (i.e., Inspections, Samples, and Visits) proposed as well as for any Options. For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated below. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

The proposal shall be submitted in such a way and in such detail as to positively identify all costs and related data in support of the cost proposal. The offeror shall identify all cost or pricing data including historical performance data. Cost or pricing data refers to the portion of the offeror's submission which is factual. The requirement for cost or pricing data is satisfied when all facts reasonably available to the Contractor up to the time of agreement on cost/price, and which might reasonably be expected to affect the price negotiations are accurately disclosed to the Contracting Officer or their representative.

In completing your proposal and supporting documents, you should consider the following:

B. Direct Materials

Your proposal should separately show any major items (those representing \$2,000 or 10% of the direct materials cost, whichever is lower) of direct materials and their estimated costs. It should also show the basis for the estimate, e.g., competitive bids, catalog prices or vendor quotations which are the basis for the proposal, and name of proposed vendors.

C. Direct Labor

Submit supporting schedules indicating types or categories of labor, together with person-hours. If you use anything other than actual hours, state the basis of the full-time equivalency, i.e., 2,000 hours, 2080 hours, etc.

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

Indicate whether current rates or escalated rates are used. If escalation is included, state the degree (percent) and methodology, e.g., annual flat rate applied to a base rate as of a specific date - or a mid-point rate for the period of performance. Include copies of salary rate schedules for all labor categories proposed.

State whether any additional direct labor (new hires) will be required during the performance period of this acquisition. If so, state the number required and anticipated date of hire.

D. Overhead, General and Administrative Expense

Unless your proposed burden rate(s) has recently been accepted by an agency of the U.S. Government, detailed projected estimates of the various items which are included in the total overhead pools are required. These projected estimates should be based upon past actuals as well as upon the planned mode and level of operation during the period in which effort is to be expended under the subject contract. These estimates should take into consideration all operating changes. Details of cost incurred in the previous fiscal year and current year to date should also be presented. If you have an approved indirect cost rate agreement, it is recommended that you attached a copy of the agreement to your proposal.

E. Special Testing

Include details of special testing (labor, material and overhead), attaching a separate schedule, if necessary. Show the basis of the estimate.

F. Special Equipment

If special purpose equipment is being proposed, provide a description of the item(s), details of the proposed cost including competitive prices, and a justification as to why the Government should furnish the equipment or allow its purchase with contract funds. (See the paragraphs below of this section for policy on equipment.)

If fabrication by the prime contract is contemplated, include details of material, labor and overhead.

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

G. Travel Expense

Attach a schedule indicating the estimated number of person-trips required, destinations, mode and cost of transportation, and the number of days of subsistence per trip. Identify and support any other special transportation costs attributable to the performance of this project.

H. Consultant Service

Consultant service should be explained by indicating the specific area in which such service is to be used. Identify the contemplated consultants. State the number of days of such service estimated to be required and the consultant's quoted rate per day, and indicate the number of hours per day in which work will be performed. State whether the consultant has received the proposed rate in performing similar services for other contractors.

I. Other Direct Costs

Special direct taxes, such as Federal excise, state franchise, or personal property taxes directly applicable to this acquisition should be identified, including basis of recovery.

Taxes from which exemptions are available to the contractor directly, or afforded the Government when the procuring agency makes available a certificate of exemption, should not be included in the cost proposal.

When the costs of materials for publication of reports required under the contract are included in your proposal, indicate the approximate total number of pages contemplated in the reports.

The cost of computer time should be supported. Explain what is included in the rate.

While the above are representative of other direct costs, they are not intended to be all-inclusive of the items which may be contained in your cost proposal.

J. Equipment

It is HHS policy that contractors will provide all equipment and

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

facilities necessary for performance of contracts. Exception may be granted to furnish government-owned property or to authorize purchase with contract funds, only when approved by the head of the procuring activity. If additional equipment must be acquired, the offeror shall include in your proposal the description, estimated cost of each item, and whether you will furnish such items with your own funds.

K. Government-Owned Property

The offeror shall identify Government-owned property in your possession and/or property acquired from Federal funds, for which you have title and is proposed to be used in the performance of the prospective contract.

L. Control of Government Property

The management and control of any Government property shall be in accordance with DHHS Publication entitled, "Contractor's Guide for Control of Government Property," dated 1990, a copy of which will be provided upon request.

M. Other Administrative Data

1. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. (If not, indicate the amount required and the anticipated source.)

2. Representations and Certifications

The Representations and Certifications (Section K) are required by public law, acquisition regulations, or acquisition policy.

One (1) copy of the Representations and Certifications, as contained in Section K of this RFP, must be completed by the offeror and returned as a part of the Business Proposal.

L-3 - 52.252-1 Solicitation Provisions Incorporated by Reference.(FEB 1998)

This solicitation incorporates one or more solicitation

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blanks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of these provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

<http://www.arnet.gov/far>

52.253-1 Computer Generated Forms. (JAN 1991)

L-4 - Solicitation Provisions Incorporated in Full Text

52.216-1 Type of Contract. (APR 1984)

The Government contemplates award of a fixed-price type contract resulting from this solicitation.

52.233-2 Service of Protest. (AUG 1996)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Food and Drug Administration
ORA Support and Assistance Management Branch, HFA-521
Attn.: Contracting Officer
5600 Fishers Lane, Room 2129
Rockville, Maryland 20857

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

Section L - Instructions, Conditions, and Notices to Offerors
(continued)

L-5 - Cost of Proposal Preparation

The solicitation does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

SECTION M - EVALUATION FACTORS FOR AWARD

The Section is non applicable to this Request for Proposal.

Attachment 1

GUIDELINES FOR STATE COVERAGE OF NLEA
UNDER FOOD INSPECTION CONTRACTS
SEPTEMBER 1994 *

The requirements of the Nutrition Labeling and Education Act will be covered by FDA in accordance with the instructions in the field assignment: "Implementation of Mandatory Nutrition Labeling Requirements" August 2, 1994. This assignment emphasizes violations involving format and observations of the label rather than analyses for the quantity of nutrients declared. The 9/20/94 memo to the FDA Districts: "Mandatory Nutrition Labeling Requirements - Amended Instructions and Additional Guidance" supplements the assignment and includes instructions for the States.

States will include NLEA coverage in their contract inspection programs in accordance with the following guidelines:

1. Collect labels from non-exempt product(s) being manufactured or labeled during a contract inspection, up to a maximum of 3 products. Obtain 4 copies of each label and include them as exhibits with the inspection report, unless otherwise instructed by the FDA District Co-Project Officer. Determine whether the product (s) are shipped in interstate commerce and include the information in the inspection report. A form letter regarding label compliance will also be left with the firm when labels are collected.
2. States with trained personnel will review the labels to determine compliance with the 5 violations being emphasized; these violations are described in the FDA field assignment. The review should be conducted by trained personnel who may be inspectors/sanitaricians, supervisors, compliance officers, etc.
3. Report the State's assessment of the labels' compliance in the inspection report or endorsement. For example, 3 labels examined and appear to be in compliance; or 2 labels examined and the label for (product name) appears to be in violation of (area of emphasis, regulation, etc).
4. The FDA District/Headquarters will review the labels to confirm the states' assessment, and to determine the appropriate follow-up. States having the authority and desire to attempt to obtain correction should discuss this with the district. Any state follow-up or regulatory actions shall be coordinated with the FDA District.

Attachment 1 (continued)

5. During routine contract surveillance inspections the States will not be required to collect physical samples of the product for state of FDA analyses. However, a state may be requested to conduct a contract reinspection to obtain a sample of a potentially violative product for FDA analysis. For example, when sample is needed to determine whether a "fat free" claim is supported, (area of emphasis No. 4).

* Edited 3/95

DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

Approved by _____
0348-0046

1. Type of Federal Action: <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	2. Status of Federal Action: <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	3. Report Type: <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change For Material Change Only: year _____ quarter _____ date of last report _____
4. Name and Address of Reporting Entity: <input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known: Congressional District, if known: _____		5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime: Congressional District, if known: _____
6. Federal Department/Agency: _____	7. Federal Program Name/Description: CFDA Number, if applicable: _____	
8. Federal Action Number, if known: _____	9. Award Amount, if known: \$ _____	
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): _____		b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI): _____
(attach Continuation Sheet(s) SF-LLL-A, if necessary)		
11. Amount of Payment (check all that apply): \$ _____ <input type="checkbox"/> actual <input type="checkbox"/> planned	13. Type of Payment (check all that apply): <input type="checkbox"/> a. retainer <input type="checkbox"/> b. one-time fee <input type="checkbox"/> c. commission <input type="checkbox"/> d. contingent fee <input type="checkbox"/> e. deferred <input type="checkbox"/> f. other; specify: _____	
12. Form of Payment (check all that apply): <input type="checkbox"/> a. cash <input type="checkbox"/> b. in-kind; specify: nature _____ value _____		
14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11: _____ _____ _____		
(attach Continuation Sheet(s) SF-LLL-A, if necessary)		
15. Continuation Sheet(s) SF-LLL-A attached: <input type="checkbox"/> Yes <input type="checkbox"/> No		
16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____	
Federal Use Only:		
Authorized for Local Reproduction Standard Form - LLL		

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in Item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

Reporting Entity: _____ Page _____ of _____